

REMARKS

Claims 4, 6-8, 10, 12-14, and 16-19 are pending in the above-identified application and stand ready for further action on the merits. In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 103(a)

The Examiner has rejected claims 4, 6-8, 10, 12-14, and 16-19 under 35 U.S.C. § 103(a) as being unpatentable over Tamura et al. '447 (US 5,827,447) in view of Kobayashi et al. '440 (US 5,869,440).

Applicants respectfully traverse. Reconsideration and withdrawal of the outstanding rejection are respectfully requested based on the following considerations.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;

- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) "obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

The Present Invention

The present claims are characterized by using an organic peracid obtained by reacting ester (A) with hydrogen peroxide (B1) in water at pH 8 to 12 and then adjusting the reaction system to pH 1 to 5. The two step pH adjustment provides the obtained organic peracid with unexpected advantages in stability and sterilizing power.

One of ordinary skill in the art would consider that an organic peracid such as CH_3COOOH and its dissociated state CH_3COOO^- would have almost the same sterilizing result as each other. Surprisingly, the present inventors have found that CH_3COOOH has a stronger sterilizing result than CH_3COOO^- . Thus, an organic peracid is an improved sterilizing chemical.

The present invention also shows that an organic peracid such as CH_3COOOH is not dissociated in an acidic condition. In the present invention, an organic peracid is produced in an alkaline state and an obtained aqueous solution thereof is adjusted to an acidic pH to stabilize the organic peracid and make it work as a sterilizer.

The sterilizing composition obtained by the method of the present invention generates an organic peracid that is effective for sterilization and provides an unexpectedly improved sterilizing result.

Distinctions over the Cited References

Tamura et al. '447 disclose a combination of a bleach-activator with a surfactant and stabilization of the bleach-activator in an aqueous solution of hydrogen peroxide. Tamura et al. '447 fail to disclose an organic peracid obtained at a pH of 8-12.

Tamura et al. '447 disclose a pH in the neutral or acidic region to stabilize a composition containing hydrogen peroxide and a bleach-activator (peracid precursor) (col. 6, lines 50-52; col. 11, line 65 to col. 12, line 3; col. 12, lines 34-35; and col. 13, lines 34-41). The bleach-activator (peracid precursor) is stabilized in an aqueous solution of hydrogen peroxide (col. 10, lines 56-59; col. 10, lines 62-67, col. 11, lines 7-10; and col. 12, lines 9-13. In the examples of Tamura et al. '447, the stability after storage is shown in terms of a residual rate of the bleach activator.

Tamura et al. '447 further disclose diluting a liquid bleach composition to generate an organic peracid (col. 11, lines 10-14). In the examples, 9.3 mL of a liquid bleach composition is added to 7 L of a washing liquid at a pH of 10.2 (col. 12, line 64 to col. 13, line 2). It would be expected that the liquid bleach composition is mixed with an alkaline washing liquid to have an alkaline pH and generate an organic peracid.

Thus, Tamura et al. '447 disclose a pH in the neutral or acidic region to stabilize a composition containing hydrogen peroxide and a bleach-activator (peracid precursor) and then, in use, an organic peracid is generated. In addition, Tamura et al. '447 disclose a combination with a surfactant with a particular index to achieve good storage stability. However, Tamura et al. '447 fail to disclose the two step pH adjustment of the present invention.

Kobayashi et al. '440 fail to overcome this deficiency. Kobayashi et al. '440 disclose activating a hydrogen peroxide bleach containing Solution A of an aqueous solution of a bleach of hydrogen peracid and Solution B of an aqueous solution of dicyandiamide and an organic or inorganic builder to activate the hydrogen peracid. However, Kobayashi et al. '440 fail to show

adjusting the pH to 1-5. Kobayashi et al. '440 merely disclose stabilization of each of the two solutions separately from each other (abstract).

In Kobayashi et al. '440, Solution A of hydrogen peroxide is preferably stored at a pH of 9.0 or lower for stabilization (col. 2, lines 36-38; col. 2, lines 26-50). A builder of Solution B is used to stabilize the peracid-activating power and enhance the activation to the peracid (col. 3, lines 10-12; and col. 3, lines 41-42). Solution A and Solution B are mixed in use, and the mixture is required to have a pH of 8.0 to 13.0 (col. 3, lines 46-49). Kobayashi et al. '440 disclose that the benefit cannot be achieved at a pH of lower than 8.0 (col. 3, lines 49-50). Thus, one of ordinary skill in the art would have no reason or rationale to adjust the pH to 1-5 after an organic peracid had been generated.

Solution B contains no peracid precursor of Tamura et al. '447. As shown in Kobayashi et al. '440, activation to a peracid means that hydrogen peroxide is decomposed in an alkali condition to obtain HOO⁻ ($\text{H}_2\text{O}_2 + \text{OH}^- \rightarrow \text{H}_2\text{O} + \text{HOO}^-$). This is not a disclosing art reference for an organic peracid.

One of ordinary skill in the art would know that a perhydroxy ion, HOO⁻, is required for bleaching. This statement is supported by the reference, **Kako Gijutsu (Process Technique)**, vol. 37, No. 5 (2002), page 326, "Bleach Technique," right-hand column, lines 12-14. This reference is enclosed herewith along with a partial English translation.

Specifically, the reference states that a bleaching action has a mechanism such that hydrogen peroxide is decomposed in an alkali region and generated hydroxyl ion receives electrons from a substance which is easily oxidized, such as a coloring matter on fiber and is oxidized and decomposed (Kako Gijutsu, page 327, left-hand column, lines 8-19). Accordingly, bleaching in the alkali region is common knowledge in the art. Therefore, it is contrary to such common knowledge to adjust the pH of the bleaching composition to an acidic region from the alkaline region.

As noted above, in Kobayashi et al. '440, the pH is preferably not more than 9 to maintain the stability of liquid A (aqueous bleaching solution). When bleaching, the pH of the mixture of Solution A and Solution B is in the alkaline region of 8.0 to 13.0. Furthermore, Kobayashi et al. '440 is not a technique using an organic peracid.

Moreover, Kobayashi et al. '440 does not disclose the two step pH adjustment of the present invention, a reaction of Component (A) with Component (B1) in water at a pH of 8 to 12 and then an adjustment of the pH to 1 to 5. The mole ratio of Component (A) to Component (B1) is limited. Kobayashi et al. '440 also do not disclose anything about the significant sterilization effect of the present invention.

Relevant to this § 103(a) rejection, *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966) has provided the controlling framework for an obviousness analysis, wherein a proper analysis under § 103(a) requires consideration of the four *Graham* factors. One such factor includes the evaluation of any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. In this regard, Applicants respectfully submit that the present invention has achieved unexpected results, whereby such results rebut any asserted *prima facie* case of obviousness. See *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). Also, the comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. See MPEP 716.02(b) and 716.02(e).

According to MPEP 2145, rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995). Office personnel should consider all rebuttal arguments and evidence presented by Applicants. See, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *In re Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990).

In this regard, the sterilizing performance of the compositions according to the present invention is superior in comparison to compositions that have not been prepared according to the claimed procedure of adapting the pH value. As such, the below table is provided for the Examiner's convenience so that a direct comparison can be made between the inventive examples and their respective closest comparative example. The table serves to help correlate data set forth in Tables 12-17 and 19-22 at pages 52, 54-58 and 62-65 of the instant specification.

STERILIZING AGENTS			STERILIZING PERFORMANCE	
Comparative Example ¹	Example ²		Comparative Example ³	Example ⁴
5-5	5-2	→	5a-1	5a-2
5-7	5-8	→	5a-3	5a-8
5-8	5-9	→	5a-4	5a-9
5-9	5-6	→	5a-5	5a-6
5-15	5-22	→	5a-6	5a-12
5-16	5-25	→	5a-7	5a-15
5-17	5-28	→	5a-8	5a-18
5-18	5-29	→	5a-9	5a-19
5-19	5-26	→	5a-10	5a-16
5-21	5-11			
5-22	5-13			
5-23	5-14			
5-24	5-17			
5-25	5-20			
5-26	5-21	→	5a-16	5a-11
5-27	5-22	→	5a-17	5a-12
5-28	5-24	→	5a-18	5a-14
5-29	5-27	→	5a-19	5a-17
5-30	5-30	→	5a-20	5a-20

¹ See Tables 15-17 at pages 56-58 of the instant specification.

² See Tables 12-14 at pages 52 and 54-55 of the instant specification.

³ See Tables 21-22 at pages 64-65 of the instant specification.

⁴ See Tables 19-20 at pages 62-63 of the instant specification.

In view of the results reported in the instant specification for the above noted Examples and Comparative Examples, the claimed procedure of adapting the pH value in two steps allows a sterilizer composition to be obtained with improved sterilizing power. Thus, due to the unexpected results as achieved by the present invention, the rejection has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

As stated in *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007), “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Furthermore, the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art. *Id.* As described above, Applicants have shown that the present invention achieves unexpected and unpredictable results.

To establish a *prima facie* case of obviousness of a claimed invention, all of the claim limitations must be disclosed by the cited references. As discussed above, Tamura et al. ‘447 in view of Kobayashi et al. ‘440 fail to disclose all of the claim limitations of independent claims 4, 10, and 13-14, and those claims dependent thereon. Accordingly, the combination of references does not render the present invention obvious. Furthermore, the cited references or the knowledge in the art provide no reason or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the outstanding rejection is respectfully requested. Any contentions of the USPTO to the contrary must be reconsidered at present.

CONCLUSION

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 4, 6-8, 10, 12-14, and 16-19 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Attachment: Kako Gijutsu (Process Technique), vol. 37, No. 5 (2002), pages 326-329 with partial English translation